



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Norfolk Division

W.L. GORE & ASSOCIATES, INC., and
GORE ENTERPRISE HOLDINGS, INC.,

Plaintiffs,
v. Civil Action No. 2:10cv441

MEDTRONIC, INC., MEDTRONIC USA,
INC., and MEDTRONIC VASCULAR,
INC.,

Defendants.

OPINION AND ORDER

Plaintiffs W.L. Gore & Associates, Inc. and Gore Enterprise Holdings, Inc. (collectively "Gore") filed this action against Defendants, Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc. (collectively "Medtronic"), alleging that Medtronic infringed upon Gore's U.S. Patent No. 5,810,870 ("the '870 patent"), entitled "Intraluminal Stent Graft." Medtronic, in turn, has asserted various affirmative defenses and counterclaims. Gore's Motion to Dismiss Medtronic's Inequitable Conduct Counterclaim, under Federal Rule of Civil Procedure 12(b)(6), is presently before the Court. For the reasons discussed below, the motion will be **DENIED**.

I. FACTUAL AND PROCEDURAL BACKGROUND

On September 3, 2010, Gore filed a complaint against Medtronic alleging patent infringement. Gore alleges that

Medtronic's Talent Thoracic Stent Graft and its Talent Abdominal Stent Grafts infringe claims 12, 16 and 19 of the '870 patent which are directed to methods of making a tubular intraluminal graft disclosed in the patent. On November 19, 2010, Medtronic filed a Motion to Dismiss Plaintiff's Complaint. On April 20, 2011, this Court denied the Defendant's Motion to Dismiss. Gore then filed an Amended Complaint on April 26, 2011, and Medtronic filed an Answer and Counterclaim on May 10, 2011.

Medtronic has asserted three counts in its counterclaim: (1) non-infringement, (2) invalidity, and (3) unenforceability due to inequitable conduct. Gore now moves to dismiss Medtronic's inequitable conduct count under Federal Rule of Civil Procedure 12(b)(6). Medtronic's inequitable conduct count can be broken into three allegations:

- (1) House and Myers (the inventors named in the '870 patent) intentionally withheld material prior art (specifically U.S. Patent Nos. 5,358,516 (the '516 patent) and 5,397,628 (the '628 patent)).
- (2) House and Myers intentionally mischaracterized references they disclosed to the Patent Office (specifically, U.S. Patent Nos. 5,123,917 (the '917 patent), 5,107,852 (the '852 patent), 4,768,507 (the '507 patent), and German Patent No. 3,918,736 (the '736 patent)).

(3) House and Myers submitted a false affidavit to the patent office by signing the standard inventor oath (stating they believed they were the "original, first and joint inventors") required to be filed with the patent application.

II. STANDARD OF REVIEW

Application of Rule 12(b)(6) in patent cases is a procedural question and is therefore governed by the law of the regional circuits. McZeal v. Spring Nextel Corp., 501 F.3d 1354, 1355-56 (Fed. Cir. 2007) ("A motion to dismiss for failure to state a claim upon which relief can be granted is a purely procedural question not pertaining to patent law. Thus, on review [this Court must] apply the law of the regional circuit."); Polymer Indus. Prods. Co v. Bridgestone/Firestone, Inc., 347 F.3d 935, 937 (Fed. Cir. 2003) (same). In the Fourth Circuit, "[t]o survive a motion to dismiss pursuant to 12(b)(6), plaintiffs' '[f]actual allegations must be enough to raise a right to relief above the speculative level,' thereby 'nudg[ing] their claims across the line from conceivable to plausible.'" Aziz v. Alcolac, Inc., 658 F.3d 388, 391 (4th Cir. 2011) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 570, (2007)). Although a court must accept the material facts alleged as true, statements of bare legal conclusions will be insufficient to state a claim. Id.

Although most unenforceability defenses need not be pled with particularity, the defense of inequitable conduct is an exception. Rule 9(b) of the Federal Rules of Civil Procedure states that: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); see Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009) (although intent may be averred generally, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"). Whether inequitable conduct has been adequately pleaded is a question of Federal Circuit law, not the law of the regional circuit, because it "pertains to or is unique to patent law." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326 (Fed. Cir. 2009) (citing Cent. Admixture Pharm. Servs. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1356 (Fed. Cir. 2007)). Thus, to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), an inequitable conduct counterclaim or affirmative defense must satisfy Fed. R. Civ. P. 9(b)'s particularity standard and "identify the specific who, what, when, where and how of the material misrepresentation or omission committed before the PTO." Exergen, 575 F.3d at 1328 (emphasis added). Although under Rule 9(b), "knowledge" and "intent" may be alleged generally, a pleading of inequitable

conduct must include sufficient facts from which a Court can "reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." Delano Farms Co. v. Cal. Table Grape Comm'n, 655 F.3d 1337, 1350 (Fed. Cir. 2011).¹ "A reasonable inference is one

¹ Charging inequitable conduct has become a common litigation tactic and recent studies have estimated that eighty percent of patent cases included such an allegation. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011). In an attempt to control the doctrine, the Federal Circuit has recently tightened the standards for finding intent and materiality. Id. at 1290. Under Therasense, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." Id. Thus, a party alleging inequitable conduct must now show "but-for materiality" and that the intent to deceive is "the single most reasonable inference able to be drawn from the evidence." Id. at 1290-91 (emphasis added).

Although Therasense has heightened the standards for inequitable conduct on the merits, it does not specifically address the pleading stage. The Court is aware that at least one district court in the Eastern District of Virginia has concluded that the heightened standards of Therasense must be incorporated and considered at the pleading stage. See Pfizer, Inc. v. Teva Pharm. USA, Inc., 2011 U.S. Dist. LEXIS 90021, *57-58 (E.D. Va. Aug. 12, 2011) (concluding that after Therasense, "a party must make an initial showing from which it may be plausibly inferred that: (1) the individual knew of the information not disclosed; (2) the information not disclosed was but-for material to the prosecution of the patent; and (3) the intent to deceive is the single most likely explanation for the non-disclosure"). However, subsequent to the Pfizer opinion, in a post-Therasense opinion, the Federal Circuit recently stated that to survive a motion to dismiss, an inequitable conduct counterclaim simply must recite "facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the

that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." Exergen, 575 F.3d at 1329. The Court must accept all allegations of material fact and construe them in the light most favorable to the nonmoving party. See Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 253 (4th Cir. 2009) (noting that in ruling on a motion to dismiss, the district court must assume all well-pleaded facts to be true).

Thus, with the above standards in mind, the Court will now assess Medtronic's three theories of inequitable conduct.

III. DISCUSSION

A. Undisclosed Prior Art

Medtronic first alleges that Wayne D. House, a Gore employee and the prosecuting attorney/agent for the '870 patent, intentionally withheld U.S. Patent No. 5,358,516 (the '516 patent) and U.S. Patent No. 5,397,628 (the '628 patent) with specific intent to deceive the PTO. (Def.'s Answer and Counterclaim ¶ 45, Docket No. 69). Medtronic similarly alleges that David J. Myers, a Gore employee and the listed inventor of the '870 patent, intentionally withheld the '516 patent with specific intent to deceive the PTO. (Id. at ¶ 48). Medtronic

PTO." Delano Farms, 655 F.3d at 1350 (citing Exergen, 575 F.3d at 1318, 1330; citing generally Therasense). Thus, this Court will follow the Delano court's recitation of the Exergen standard, without any modification for the heightened Therasense requirements, as it is binding precedent on this Court.

argues that the '870 patent application represented to the PTO that the "crux" of the invention and the improvement over prior art was an ePTFE covering less than 0.10mm thick. Medtronic alleges that, notwithstanding this representation to the PTO, both Mr. House and Mr. Myers were aware that Gore already had the capability of making ePTFE coverings that were less than 0.10mm thick and had already been using such coverings in other patented implantable medical devices (specifically, the '516 and '628 patents). (Id. at ¶ 51-62). Thus, Medtronic argues that Mr. House and Mr. Myers falsely represented to the PTO that ePTFE coverings less than 0.10mm did not exist in the prior art.

Gore argues that Medtronic's allegations concerning the '516 and the '628 patent are pled solely on information and belief and contain nothing more than conclusory allegations that these references were "material" to the patentability of the '870 patent. Specifically, Gore argues that the '516 and the '628 patents describe vastly different technologies than the '870 patent. The '516 patent discloses a wire carrying an electrical current that is coated with a thin layer of ePTFE for insulation. (Id. at Ex. B, Docket No. 69-2; '516 patent col 1:37-43). The '628 patent discloses a "rubber body protection material" whose purpose is to "increase the wearing comfort of cellular rubber wet suits and orthopedic braces." (Id. at Ex. C, Docket No. 69-3; '628 patent col 1:54-57). Gore also argues

that it is clear from the specification of the '870 patent that the '516 and the '628 patents would not be material to patentability. Specifically, the specification of the '870 patent refers to U.S. Patent No. 3,953,566 (the '566 patent) which discloses an ePTFE film that is less than 0.10mm thick.² Thus, Gore argues that Medtronic's basis for alleging the '516 and '628 patents are material is contradicted by the patent itself. Last, Gore argues the reasonableness of Medtronic's allegations are contradicted by the prosecution history of the '870 patent since the patent examiner instructed the applicants to "eliminate irrelevant and marginally pertinent cumulative references."³

The first element of an inequitable conduct claim is misrepresentation of a material fact. At the motion to dismiss stage, Medtronic must merely allege a plausible and specific claim from which a reasonable jury could infer that Mr. House

² The '566 patent was issued in 1976 and discloses a "process for producing porous products." Medtronic argues that it is improper for the Court to consider the '566 patent since it was not attached as an exhibit to Medtronic's counterclaim. The Court need not address this issue because it does not rely on the '566 patent in assessing the sufficiency of the pleading.

³ Again, Medtronic argues that it is improper for the Court to consider the '870 patent's prosecution history as it was not attached as an exhibit to Medtronic's counterclaim. However, the '214 patent application is already part of the record and was attached to plaintiff's opening claim construction brief as part of a joint appendix. (Pl. Claim Construction Brief, Ex. 3, Docket No. 66-3). Nevertheless, the Court does not rely on the '214 application in ruling on the motion.

and Mr. Myers knew of the prior use, appreciated that the prior use was material, and decided not to disclose that information with deceptive intent. Delano, 655 F.3d at 1350. Medtronic has, in a detailed manner, identified the specific "who, what, when, where, and how" of the alleged misrepresentation. Exergen, 575 F.3d at 1328. Medtronic has referred to specific examples of prior art that Gore did not cite, detailed why those omissions are material and not cumulative, and how one could infer Mr. House and Mr. Myers were aware of the undisclosed patents and their potential materiality.

The second element of an inequitable conduct claim is intent to deceive. Because exclusion of material prior art could provide a patent applicant with the significant benefit of having the application granted, Medtronic has also pled sufficient facts upon which a reasonable inference of intent to deceive could be based. The strength of these inequitable conduct arguments will ultimately hinge on whether the prior art cited by Medtronic is material and non-cumulative. See Alloc, Inc. v. Pergo, Inc., 366 Fed. Appx. 173, 176 (Fed. Cir. 2010) (noting that information is material when a reasonable examiner would consider it important in issuing a patent; but also noting that "information is not material if it is cumulative of other information already disclosed"). However, the cumulative determination will require a fuller record and is

not a proper inquiry at the 12(b)(6) stage. Although the facts alleged in Medtronic's counterclaim may not be enough to satisfy the Therasense elements by clear and convincing evidence, the alleged facts are sufficient to satisfy Exergen's pleading requirements. Therefore, this inequitable conduct claim will not be dismissed.

B. Mischaracterized Prior Art

Next, Medtronic alleges that Gore engaged in inequitable conduct by materially misrepresenting that the problem for solution by the '870 patent was "a stent with a thinner covering of ePTFE" when Mr. House knew that the '917 patent, the '852 patent, the '507 patent, and the '736 patent all disclosed the use of thinner ePTFE coverings "with medical devices." (Def. Answer and Counterclaim, ¶ 46, Docket No. 69). Similarly, Medtronic alleges that Mr. Myers also intentionally mischaracterized material information and engaged in a pattern of deception by alleging the '870 patent solved the problem of creating a stent with thinner coverings when he knew the '516 and the '852 patent already disclosed the use of a thinner ePTFE covering "with medical devices." (Id. at ¶ 49).

In response, Gore first argues that the '870 patent's "sole improvement" over the prior art is not an ePTFE covering of less than 0.10mm as Medtronic states. Gore notes that the '870 patent describes a stent graft with various features such as a

diametrically adjustable stent, a covering less than 0.10mm, a covering on the exterior surface, and a seam extending from the exterior surface through the luminal surface. Gore argues that Medtronic therefore improperly elevates the importance of one attribute over the others. Second, Gore argues that Medtronic's allegations that Mr. House and Mr. Myers intentionally "mischaracterized" these prior patents are conclusory and pled on information and belief. Gore points out that Medtronic concedes that each of these patents was submitted to the PTO during the prosecution of the '214 application (the '892 parent patent application) and cites to the actual '214 application to demonstrate the examiner considered and initialed the prior art before issuing the patent. (Pl. Ex. 1, 23680-88). Thus, Gore argues that Medtronic's allegations that they deliberately mischaracterized these references simply do not make sense because Gore disclosed these very references to the Examiner.

The Court finds Medtronic has satisfied the Rule 9(b) pleading standards by identifying the alleged misrepresentation, why the misrepresentation was material, and has pled sufficient facts to support a reasonable inference of intent to deceive. Taking the facts in the light most favorable to the non-moving party, Medtronic has alleged that House and Myers were both involved with these prior art patents (as inventors or prosecuting agents), and thus they were aware that Gore already

had the capability of manufacturing ePTFE coverings less than 0.10mm thick. Yet, Medtronic alleges that with this knowledge, House and Myers still characterized the '870 patent as solving the "thick bulky wall" problem of past stents. To ultimately determine whether this alleged mischaracterization was material and made with intent to deceive will require actual evidence, not just argument. However, taking the facts in the light most favorable to the non-moving party, Medtronic was thorough in its pleading and has satisfied the Rule 9(b) pleading requirements. Therefore this inequitable conduct claim will not be dismissed or stricken at this stage.

C. False Affidavit

In Medtronic's last inequitable conduct allegation, they accuse both Mr. House and Mr. Myers of intentionally filing a false affidavit. Medtronic alleges that Mr. House filed a false affidavit as an alleged inventor by stating he believed he was the "original, first and joint inventor of the subject matter" when he knew the '516, '628, '917, '852, '507, and '736 patents all disclosed the use of ePTFE coverings less than 0.10mm with medical devices. (Def. Answer and Counterclaim, ¶ 47, Docket No. 69). Additionally, Medtronic similarly alleges that Mr. Myers filed a false affidavit as the first and joint inventor of the subject matter since he knew the '516 and the '852 patent

already disclosed the use of a thinner ePTFE covering with medical devices. (*Id.* at ¶ 50).

Gore has argued that the declaration on which Medtronic is relying is something that every inventor is required to sign before submitting a patent application. Thus, Gore posits, if the Court accepts Medtronic's argument, every single allegation of failure to disclose would trigger a false affidavit allegation.

Because the Court has found the previous two inequitable conduct allegations sufficient, the Court finds that this last allegation also satisfies Rule 9(b)'s pleading standards. If Mr. House and Mr. Myers were aware of prior art that disclosed ePTFE coverings less than 0.10mm thick, knew the prior art could be material to the patentability and still intentionally failed to disclose or mischaracterized those patents, then it is reasonable for the Court to also infer that Mr. House and Mr. Myers intentionally filed a false affidavit by signing the inventors oath with that knowledge. As stated above, although the allegations alone may not be sufficient to win on the merits under Therasense's heightened standards, the facts alleged are sufficient for the Court to find that the individuals "knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive." Delano, 655 F.3d at 1350. Thus, the false affidavit inequitable

conduct allegation will also not be dismissed or stricken at this time.

IV. CONCLUSION

For the reasons discussed above, Gore's Motion to Dismiss Medtronic's Inequitable Conduct Counterclaim is **DENIED**.

The Clerk is **REQUESTED** to send a copy of this Opinion and Order to counsel of record for the parties.

It is so **ORDERED**.

/s/MSD
Mark S. Davis
UNITED STATES DISTRICT JUDGE

Norfolk, Virginia
February 3, 2012